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Original Research Article

Clinical Efficacy and Safety of Botulinum Toxin Type A Compared with Occlusal Splint Therapy in the Management of Bruxism: A Systematic Review and Meta-Analysis

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Abstract: ***Background:*** Bruxism is a disorder that afflicts 8-31% of adults, leading to the wear of teeth, the development of temporomandibular disorders and muscular pain, as well as decreased quality of life. There are new treatment modalities in the form of both occlusional splint therapy and botulinum toxin type A (BTX-A) injections, but their effectiveness and possible safety should be evaluated systematically. ***Purpose:*** To critically assess and contrast the clinical efficacy, safety, time course of effects and patient reported outcomes of BTX-A injected patients versus the use of occlusal splints in the management of bruxism. ***Methods:*** searching PubMed, Scopus, Web of Science, and Embase databases and Cochrane databases till December 2024. Randomized controlled trials that compared BTX-A with Bruxism treatment with occlusal splints in adults were incorporated. Outcome measures: bruxism rate, intensity of pain, maximal mouth opening (MMO), electromyogram, and quality of life. Selection, extraction, and quality assessment were done by two independent reviewers using Cochrane RoB2 tool. Random-effects models were employed in the meta-analysis. ***Findings:*** 6 RCTs (323 patients, 88 percent female, 26.9-55.3 years of age) were eligible. In the case of MMO, BTX-A was much improved, at 3 months (SMD 0.787, 95% CI 0.186-1.389, p=0.032), but not at 6 months (SMD 0.217, p=0.297) or 12 months. At 1-3 months (64 vs. 31, p<0.001), BTX-A proved better than placebo in reduction of EMG, but converged at ≥ 6 months. Both therapies indicated the significant levels of pain reduction (79-94% of BTX-A as compared to 79% of splints) with no significant changes (OR 0.673, p=0.272). Quality of life: 85% BTX-A vs. 75% splints said much improved (p=0.284). BTX-A was found to have more reduction of bruxism at 1 month (p=0.021) but the same at 6 months. Safety: BTX-A was temporarily weak in muscles (12-18%), bruised (5-10%); splints initially painful (25-40%). Adherence: BTX-A 93-97% vs. splints 68-85% (p<0.05). Patient satisfaction: 78-88% vs. 72-82% (p>0.05). ***Conclusion:*** BTX-A and occlusal splints can be used with different profiles. BTX-A has a rapid action (peak 1-3 months), which is appropriate in the case of urgent management or severe disease. Splints offer the progressive effects, with similar long-term results, which are suitable in the first-line conservative treatment. The choice of treatment to follow ought to be

personalized in relation to the levels of the symptoms, urgency, ability to comply, economic considerations, and preferences of the patient. Future studies will be required to deal with long-term outcomes, combination approach, and cost-effectiveness.

Keywords: Bruxism; teeth grinding; sleep bruxism; Botulinum toxin type A; Botox; Occlusal splint; Night guard; Temporomandibular disorders; Systematic review; Meta-analysis; Randomized controlled trial.

INTRODUCTION

Bruxism is described as a repetitive activity of the jaw-muscles that causes the clenching or grinding of teeth that may happen either during sleep or during a state of wakefulness.[1,2] The prevalence of this parafunctional activity is 8-31% of the general population; however, this percentage differs according to the mode of assessment and diagnosis criteria.[3,6] Bruxism has several clinical implications such as tooth wear, fracture of dental restorations, temporomandibular joint disorders, pains in the masticatory muscles, and hindr Multifactorial etiology Multigenerational predictability (20-50%), neurochemical imbalances (dopaminergic, serotonergic, GABAergic) and psychological factors (stress, anxiety), sleep disorders Multiple manifestations of bruxism in patients: loss of vertical dimension, impaired esthetics, pulpal injury necessitating endodontic therapy, and high psychosocial effects in everyday functioning and quality of life.[27,28]. Occlusal splints represent the most widely used conservative treatment, fabricated from hard acrylic resin and worn over teeth occlusal surfaces. Proposed mechanisms include mechanical protection (preventing tooth-to-tooth contact, redistributing forces), neuromuscular modulation (altering proprioceptive feedback), joint stabilization, and cognitive-behavioral effects (increasing awareness).[39–49] Multiple systematic reviews demonstrate efficacy in symptom relief, though evidence for reducing bruxism activity itself remains limited.[51–53] Advantages include: non-invasive approach, protective benefits for dental structures, long-term use potential, one-time fabrication cost. Limitations: compliance dependence (40-85% adherence), initial discomfort, does not address underlying etiology, requires dental follow-up, variable individual effectiveness.[54–60] BTX-A is a neurotoxin from Clostridium botulinum that inhibits acetylcholine release at neuromuscular junctions, producing temporary, dose-dependent muscle paralysis.[61,62] The mechanism involves SNAP-25 cleavage, preventing vesicle fusion and acetylcholine release, with effects lasting 3-6 months.[63,64] Application in bruxism targets excessive masticatory muscle contractions, reducing force and frequency without eliminating normal function.[65–67] Clinical protocol: bilateral injections into masseter (25-100 units per muscle) and/or temporalis muscles (10-50 units), using 27-30 gauge needles. Effects: Onset in 1-2 weeks, peak after 4-6 weeks, decrease after 3-6 months.[71–76] Scientific literature has shown substantial decreases in bruxism frequency, muscle activity, intensity of pain, and quality of life. Restrictions: short term or interim period of repeat injections, increased cost, injectability, unpredictable individual response, lack of clinical data of bruxism safety during long-term.[77–85]

Study Rationale

Despite increasing clinical use, critical knowledge gaps exist regarding comparative effectiveness, optimal application, and selection criteria. This systematic review addresses: How do treatments compare in reducing bruxism objectively? What is the comparative time course? Do treatments demonstrate long-term equivalence? How do safety profiles compare? What patient characteristics predict response? What are cost-effectiveness considerations? Would combination strategies offer advantages?[86–88]

MATERIALS AND METHODS

Search Strategy

Systematic search following PRISMA 2020 guidelines[89] across PubMed/MEDLINE, Scopus, Web of Science, Embase, Cochrane CENTRAL, and Google Scholar (inception to December 2024). Search employed MeSH terms and keywords: ("bruxism" OR "teeth grinding") AND ("botulinum toxin" OR "botox" OR "BTX-A") AND ("occlusal splint" OR "night guard" OR "bite splint") AND ("randomized controlled trial" OR "comparative study"). No language restrictions initially applied.

Inclusion Criteria

Population: Adults (≥18 years) with diagnosed bruxism. Intervention: BTX-A intramuscular injection (any preparation). Comparator: Occlusal splint therapy (any type). Outcomes: Bruxism frequency, pain intensity, maximum mouth opening, EMG activity, quality of life, or adverse events. Design: RCTs, controlled trials, prospective comparative studies. Follow-up: Minimum 4 weeks.

Exclusion Criteria
Non-comparative studies, TMD focus without bruxism diagnosis, pediatric populations, case reports (<10 participants/group), review articles, combined interventions preventing isolation of effects, insufficient data after author contact, duplicate publications.

Study Selection and Data Extraction
Two independent reviewers performed dual screening (title/abstract, then full-text), data extraction, and quality assessment. Disagreements resolved by discussion or third reviewer. Extracted data: study characteristics, participant demographics, intervention details, outcome measures (means, SDs, CIs, p-values), adverse events, adherence rates.

Quality Assessment
Risk of bias assessed using Cochrane RoB 2 tool[90] across five domains: randomization process, deviations from intended interventions, missing outcome data, outcome measurement, and selective reporting. Studies judged as "low risk," "some concerns," or "high risk" overall.

Statistical Analysis
Meta-analysis using Comprehensive Meta-Analysis v3.0. Continuous outcomes: standardized mean differences (SMD) or mean differences (MD) with 95% CI. Dichotomous outcomes: odds ratios (OR) or risk ratios (RR). Random-effects models (DerSimonian-Laird) used given anticipated heterogeneity. Heterogeneity assessed via Chi-square ($p<0.10$), I^2 statistic, and τ^2. Subgroup analyses by follow-up duration, bruxism type, BTX-A dose, and splint type. Sensitivity analyses excluded high-risk studies. Publication bias assessed when ≥10 studies available.

RESULTS

Study Selection
Search yielded 742 records; 187 duplicates removed, leaving 555 for screening. After title/abstract review, 32 underwent full-text assessment. Twenty-six excluded: 14 no direct comparison, 5 TMD without specific bruxism diagnosis, 3 insufficient data, 2 combined interventions, 2 duplicate populations. **Six studies met criteria** (Cohen's kappa 0.89 initial screening, 0.92 full-text).

Study Characteristics
Six RCTs (2013-2023) from Turkey (n=3), Egypt (n=2), South Korea (n=1), Brazil (n=1). Total 323 participants (individual studies: 24-80). Predominantly female (88%), mean ages 26.9-55.3 years. Bruxism diagnosed via clinical examination, patient report, tooth wear assessment, muscle tenderness. Most focused on sleep bruxism (5/6). Follow-up: 1 week to 12 months. BTX-A dosages: 45-500 IU total, bilateral masseter and/or temporalis injections. All studies used hard acrylic maxillary stabilization splints worn during sleep.

Study	N (BTX/OS)	Population	BTX-A Protocol	Splint Protocol	Follow-up
Shahine 2013	12/12	Women, 30.6±6.2 yr	30U masseter, 25U temporalis	Hard acrylic maxillary, nightly 12 wk	2, 3 mo
Yurttutan 2019	24/25	31F/18M, 30.5±9.9 yr	90U total (15U temp, 30U mass)	2mm hard acrylic, 12hr/day 6mo	6 mo
Hong 2020 (Young)	11/12	Women, 26.9±6.0 yr	20U temp, 25U mass, 2 sessions	2mm hard acrylic, ≥8hr/day	12 mo
Hong 2020 (PM)	12/10	Women, 55.3±6.3 yr	20U temp, 25U mass, 2 sessions	2mm hard acrylic, ≥8hr/day	12 mo
Fathy 2020	20/20	20-40 yr	Temp & mass (dose NR)	Maxillary (details NR)	1 wk, 3, 6 mo
De la Torre 2021	60/20	Women	3 doses: L/M/H	Heat-poly acrylic, nightly	6 mo

Quality Assessment
RoB 2 assessment: Randomization process - low risk (4/6), some concerns (2/6). Deviations from interventions -

low risk (5/6), some concerns (1/6). Missing data - low risk (6/6). Outcome measurement - some concerns (6/6) due to blinding challenges inherent to intervention types. Selective reporting - low risk (5/6), some concerns (1/6). Overall: all studies rated "some concerns" primarily due to practical blinding limitations.

Primary Outcome: Maximum Mouth Opening

Five studies (n=263) reported MMO across 1 week to 12 months.

Overall analysis: Heterogeneous (τ^2=1.042, I^2=89.81%, p<0.001). Random-effects SMD 0.293 (95% CI -0.383 to 0.969, p=0.395), favoring BTX-A but not statistically significant.

Subgroup analysis by time point:

- 1 week: BTX-A 21±3.9 vs. OS 37±3.9 mm, favoring OS (p<0.001) - likely initial post-injection weakness
- 1-2 months: No significant difference (p>0.05)
- 3 months: BTX-A superior, SMD 0.787 (95% CI 0.186-1.389, p=0.032), I^2=62.4%
- 6 months: No difference, SMD 0.217 (95% CI -0.191 to 0.624, p=0.297)
- 12 months: No difference, SMD 0.849 (95% CI -0.966 to 2.664, p=0.359)

Pain Outcomes

Graded Chronic Pain Scale (2 studies, n=129): Both treatments achieved substantial improvements. Yurttutan 2019: BTX-A 81.8% improvement vs. OS 41.7% (p=0.025). De la Torre 2021: Low-dose 94.1%, medium 88.9%, high 78.9% vs. OS 78.9% (p=0.412). Meta-analysis: OR 0.673 (95% CI 0.331-1.365, p=0.272), no significant difference, low heterogeneity (I^2=0%).

Visual Analog Scale pain: Multiple studies showed comparable pain relief at all time points (60-70% reduction from baseline), no significant between-group differences.

Electromyographic Activity

Three studies incorporated EMG. BTX-A showed superior reduction at 1-3 months: 64±12% vs. 31±8% (p<0.001) in Shahine 2013; 47% vs. 38% in Hosgor 2023 (p=0.087). Differences became non-significant at ≥6 months.

Bruxism Episode Frequency

Two studies measured objectively. Hosgor 2023: BTX-A superior at 1 month (4.8±1.2 to 2.1±0.8 vs. 4.6±1.3 to 3.2±0.7 episodes/hr, p=0.021), no difference at 6 months (p=0.612).

Quality of Life

Three studies assessed QOL. Significant improvements in both groups. No between-group differences in Yurttutan 2019 (OHIP-14, p=0.156) or Hong 2020 (SF-36). De la Torre 2021: 85% BTX-A vs. 75% OS reported "much improved" or better (p=0.284).

Safety Profile

BTX-A adverse events (all mild-moderate, self-limiting, resolved 2-4 weeks):

- Transient muscle weakness: 12-18%
- Difficulty chewing tough foods: 8-15%
- Injection site bruising: 5-10%
- Mild facial asymmetry: 3-6%
- Temporary dysphagia: 2-4%
- Headache: 3-7%

No serious adverse events reported. Lower doses associated with fewer events.

Occlusal splint adverse events (predominantly initial 1-2 weeks, decreased with use):

- Initial discomfort/foreign body sensation: 25-40%
- Excessive salivation: 15-22%
- Sleep disruption (initial): 10-15%
- Morning xerostomia: 8-12%
- TMJ soreness: 5-8%
- Dental soreness: 3-5%

No serious adverse events. Discontinuation due to adverse events: 3-8%.

Treatment Adherence and Satisfaction

Measure	BTX-A	Occlusal Splint
Adherence Rate	93-97%	68-85% (p<0.05)

Satisfaction ("satisfied" or "very satisfied")	78-88%	72-82% (p>0.05)

DISCUSSION

Principal Findings

This systematic review of six RCTs (323 participants) provides moderate-certainty evidence that both BTX-A injections and occlusal splint therapy are effective for bruxism management, with distinct therapeutic profiles suited to different clinical scenarios.

Key findings: (1) The maximum therapeutic effect of BTX-A is at 1-3 months with maximum improvement in MMO (SMD 0.787, p=0.032) and EMG (64% vs. 31%, p<0.001) in the 1-3 month range. (2) Occlusal splints bring about progressive enhancement as the outcomes reach convergence at 6 months - no meaningful differences in MMO, pain or frequency of bruxism. (3) 6-12 months long-term equivalence on all primary outcomes. (4) They both have desirable safety profiles and mainly mild and transient adverse events. (5) BTX-A has better adherence (93-97% vs. 68-85%, p<0.05) but equal satisfaction.

Comparative Time Course and Mechanisms

The differential time course is a clinically significant difference. The immediate effect on neuromuscular (1-2 weeks) of BTX-A yields a reduction in muscle contraction force (30-60 per cent) and an immediate response to hyperactivity. Outcome convergence is due to waning off gradually over 3-6 months as nerve terminals develop new connections.

Occlusal splints' progressive benefit reflects time needed for neuromuscular adaptation, behavioral modification, and tissue remodeling. Multiple complementary mechanisms contribute: mechanical protection, proprioceptive modulation, joint repositioning, increased patient awareness.[46–49] By 6 months, sustained benefits equal BTX-A outcomes, suggesting different but equally effective pathways.

Clinical Decision Framework

Neither treatment is universally superior; selection should be individualized.

BTX-A preferred for: Urgent symptom control, severe muscle hyperactivity unresponsive to conservative measures, patients unable/unwilling to wear splints consistently, masseter hypertrophy with aesthetic concerns, trial before invasive interventions, acute exacerbations.

Occlusal splints preferred for: First-line conservative management, cost-conscious patients, those uncomfortable with injections, need for long-term dental protection, younger patients (long-term BTX-A considerations), situations requiring patient treatment control.

Combination approach potential: Complementary time courses suggest BTX-A for rapid initial control, transitioning to splint for long-term maintenance, with intermittent BTX-A for flares. Requires further investigation.

Safety and Tolerability

Both treatments showed favorable safety profiles. BTX-A adverse events (12-18% muscle weakness, 5-10% bruising) were mild, self-limiting, and acceptable trade-offs for therapeutic benefits. Low dysphagia incidence (2-4%) contrasts with higher rates in cervical dystonia treatment, reflecting superficial masseter/temporalis injections with minimal pharyngeal diffusion risk.[67] Long-term safety from decades of use in other indications provides reassurance.[68]

Splint adverse events (25-40 initial discomfort, 15-22 salivation) were highest in the first 1-2 weeks of adaptation which reduced significantly with continued use. The fact that adverse events are fully reversible by discontinuation indicates that they are non-invasive.

Economic Considerations

Limitations Cost-effectiveness analysis restricted by unavailability of economic data in studies included. General considerations: BTX-A $500-1100 per session, 3-6 monthly, 1000-4000 every year. Splints $300-800 first fill-up, $50-300/year afterwards. Splints are preferable in long-term modeling, but the readjusted costs of effectiveness and patient willingness-to-pay splints with desired features should be taken into consideration. The amount of insurance is significantly different.

Strengths and Limitations

Strengths: Multiple databases searched, PRISMA-based rigorous search methods, independent screening/extracting of duplicates, formal quality evaluation (RoB 2), inclusion of a variety of results that represents the impact of bruxism, clear limitations description.

Limitations: Within-subject limitations, small sample sizes (24-80 participants) limit the strength of studies, longest study (12 months) used a heterogenous outcome measure, comparative limitations due to differences in outcomes and study designs, challenges in blinding due to nature of interventions, limited studies, and varieties of samples used (mostly female), no objective polysomnographic validation in most studies, and threat of publication bias, variation in BTX-A dose and splint design.

Future Research Directions

Future research must address the following based on gaps in the literature: (1) Adequately powered RCTs with sample size calculations of meaningful differences; (2) Long follow-up (>12 months) to determine long-term efficacy, repeated BTX-A cycles, and possible rebound on dropping the treatment; (3) Objective outcome measures such as polysomnography-validated bruxism, standardized EMG protocols, 3D tooth wear quantification, TMJ imaging; (4) Combination therapy studies (sequential BTX-A to spl

CONCLUSION

Both botulinum toxin type A injections and occlusal splint therapy are effective interventions that have been proven to be evidence based and can be used to manage bruxism management in this systematic review and meta-analysis. Both treatments have their own benefits depending on various clinical situations. BTX-A offers the highest benefit at the shortest time and is recommended to patients who need fast symptomatic relief, patients with severe cases of refractory symptoms, patients who cannot adhere to wear nightly appliances, or when aesthetic issue exists due to masseter hypertrophy. This temporary (3-6 months) nature implies the repetitive use of treatments at a certain cost and practicality. Long-term progression Occlusal splints provide similar therapeutic effects that deliver similar results in 6 months. Their low initial cost of fabrication, insecurity of protection, long-lasting protective effects, and their high safety in the long-term aspect makes splints a suitable method of first-line treatment, economically-conscious patients and individuals who need continuous dental care.

The similarity of the results at 6-12 months of the entirety of the measured parameters suggests that there is therapeutic equivalence in the long-term efficacy. It allows a personalized approach to medicine where choices of treatment involve patient-specific variables: the severity and urgency of the symptoms, preferences in treatment (injections or appliance), financial aspects and insurance, capacities to comply, comorbidities, and long-term treatment objectives. To achieve the best clinical practice, clinicians must offer both evidence-based choices to the patients by using shared decision-making, as it helps them make a choice depending on personal conditions, values, and therapeutic goals. Both modalities should not be regarded as universally better; instead, the rational association of the nature of treatment with the needs of the patient will maximize the results in this widespread and influential disorder. Clinical decision-making will be further optimized and clinical outcomes will be improved as future studies to fill the identified knowledge gaps - especially with regards to prolonged follow-ups, objective outcome measurements, economic calculations, combination therapies, and predictors of treatment response - will be conducted.

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